

Practitioner's Docket No. 2605/101**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of _____
Inventor(s)for _____
Title of invention**OR**

In re application of: Miyata et al.

Application No : 10/018,311
Filed: October 30, 2001
For: Meg-3 proteinGroup Art Unit: N/A
Examiner: N/A**Commissioner for Patents
Washington, D.C. 20231****TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN
THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office *if* filed by the applicant, (1) within three months *of* the filing date *of* a national application; (1) within three months *of* the date *of* entry *of* the national stage as set forth in § 1.491 In an International application; or (3) before the mailing date *of* a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b)

CERTIFICATE of MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Date: February 7, 2002

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office.

SignatureHarriet M. Strimpel, D.Phil.
(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office Action [6-3]--page 1 of 2)

NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosures statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

Reg. No.: 644658

Signature of Practitioner

Tel. No : 617/443-9292

Harriet M. Strimpel, D.Phil.
(type or print name of practitioner)

Customer No.: (00)-2101

Bromberg & Sunstein LLP
125 Summer Street, Boston, MA 02110

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office Action [6-3]--page 2 of 2)

Practitioner's Docket No. 2605/101**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of _____
Inventor(s)for _____
Title of invention**OR**

In re application of: Miyata et al.

Application No.: 10/018,311

Group Art Unit: N/A

Filed: October 30, 2001

Examiner: N/A

For: Meg-3 protein

**Commissioner for Patents
Washington, D.C. 20231****INFORMATION DISCLOSURE STATEMENT****CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10****(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)**37 C.F.R. § 1.10***

- ☒ with sufficient postage as first class mail.

- ☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ **(mandatory)****TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: February 7, 2002

Signature _____

Harriet M. Strimpel, D.Phil.

(type or print name of person certifying)

(Information Disclosure Statement [6-1]--page 1 of 6)



NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(d).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard *unused* sections and number pages consecutively)

- 1 ☒ Preliminary Statements
- 2 ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
- 3 ☐ Statement as to Information Not Found in Patents or Publications
- 4 ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
- 5 ☐ Cumulative Patents or Publications
- 6 ☒ Copies of Listed Information Items Accompanying This Statement
- 7 ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. EPO Search Report
 - 7B. English Language Version of EPO Search Report
- 8 ☐ Translation(s) of Non-English Language Documents
- 9 ☐ Concise Explanation of English Language Listed Information Items (Optional)
- 10 ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**Section 1. Preliminary Statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miyata et al. Attorney Docket: 2605/101
 Serial No: 10,018,311 Art Group Unit: N/A
 Date Filed: October 30, 2001 Examiner Name: Not Assigned
 Invention: Meg-3 protein

**LIST OF PATENTS AND PUBLICATIONS FOR
 APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

International Patents

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
_____	AA	EP 0780472 A2	25.06.1997	Ikeda et al.	C12N 15/12
_____	AB	WO99/33981	08.07.1999	Lal et al.	C12N 15/12

Other Documents

Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
_____	AC	Yasuda et al.	Functional Quantitative Analysis of the Genome in Cultured Human Mesangial Cells, Kidney Int., Vol. 53, No. 1, pages 154-158, 1998
_____	AD	Miyata et al.	A Mesangium-predominant Gene, Megsin, Is a New Serpine Upregulated in IgA Nephropathy, J. Clin. Invest., Vol. 120, No. 4, pages 828-836, 1998
_____	AE	Terada et al.	Gendai Iryo, Vol. 32, No. 3, pages 745-750, 2000

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

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Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:

"A legible copy of.:

- (i) Each U.S. patent application publication and U.S. and foreign patent;
- (ii) Each publication or that portion which caused it to be listed,
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.



Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type or print name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

(type or print name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
- ☒ in the practitioner's file.

Reg. No.: 644658

SIGNATURE OF PRACTITIONER

Tel. No.: 617/443-9292

Harriet M. Strimpel, D.Phil.
(type or print name of practitioner)

Customer No.: 00-2101

Bromberg & Sunstein LLP
125 Summer Street, Boston, MA 02110

(Information Disclosure Statement-Section 10. Identification of Person(s) Making This Information Disclosure Statement [6-1]-page 6 of 6)